

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NALOX-1 PHARMACEUTICALS, LLC,
Petitioner,

v.

ADAPT PHARMA OPERATIONS LIMITED, AND
OPIANT PHARMACEUTICALS, INC.
Patent Owners.

CASE IPR2019-00688
U.S. Patent No. 9,468,747

**PETITIONER NALOX-1 PHARMACEUTICALS, LLC'S
UPDATED EXHIBIT LIST**

TABLE OF EXHIBITS

| Exhibit Number | Description |
|-----------------------|---|
| Nalox1001 | U.S. Patent No. 9,468,747 (the '747 patent) |
| Nalox1002 | Expert Declaration of Maureen Donovan |
| Nalox1003 | Expert Declaration of Günther Hochhaus |
| Nalox1004 | Excerpt of File History of U.S. Patent No. 9,561,177, Aug. 22, 2016 Office Action, Non-Final Rejection (Aug. 22, 2016 Non-Final Rejection) |
| Nalox1005 | Excerpt of File History of U.S. Patent No. 9,561,177, Oct. 21, 2016 Amendment and Response to Office Action (Oct. 21, 2016 Response to Office Action) |
| Nalox1006 | Excerpt of File History of U.S. Patent No. 9,561,177, Dec. 21, 2016 Office Action, Notice of Allowance and Fees Due (Notice of Allowance) |
| Nalox1007 | U.S. Patent No. 9,192,570 (Wyse) |
| Nalox1008 | Chinese Patent No. 1,575,795 (Wang) |
| Nalox1009 | PCT International App. Pub. No. WO00/62757 (Davies) |
| Nalox1010 | Djupesland, P., <i>Nasal Drug Delivery Device: Characteristics and Performance in a Clinical Perspective - A Review</i> , 3 Drug Deliv. & Transl. Res. 42–62 (2013) (Djupesland) |
| Nalox1011 | Grassin-Delyle, S. et al., <i>Intranasal Drug Delivery: An Efficient and Non-invasive Route for Systemic Administration, Focus on Opioids</i> , 134 Pharm. & Ther. 366–79 (2012) (Grassin-Delyle) |
| Nalox1012 | Handbook of Pharmaceutical Excipients, 56–60, 64–66, 78–81, 220–22, 242–44, 270–72, 441–45, 517–22, 596–98 (Rowe, R. et al. eds., 6th ed. 2009) (HPE) |
| Nalox1013 | Kushwaha, S. et al., <i>Advances in Nasal Trans-Mucosal Drug Delivery</i> , (1)7 J. Applied Pharm. Sci. 21–28 (2011) (Kushwaha) |
| Nalox1014 | U.S. Patent No. 5,866,154 (Bahal) |
| Nalox1015 | U.S. Patent No. 8,198,291 (the '291 patent) |

| Exhibit Number | Description |
|-----------------------|--|
| Nalox1016 | Wermeling, D., <i>A Response to the Opioid Overdose Epidemic: Naloxone Nasal Spray</i> , 3 Drug Deliv. & Transl. Res. 63–74 (2013) (Wermeling 2013) |
| Nalox1017 | Alabama Department of Public Health, <i>Alabama EMS Patient Care Protocols</i> (7th ed., Oct. 2013) (Alabama EMS Protocols) |
| Nalox1018 | Aptar Pharma, Press Release, Aptar Pharma Provides Unit-Dose Nasal Spray Technology for Treatment of Opioid Overdose (Apr. 20, 2016) (Aptar Press Release) |
| Nalox1019 | Ashton, H. et al., <i>Best Evidence Topic Report Intranasal Naloxone in Suspected Opioid Overdose</i> , 23(3) Emerg. Med. J. 221–23 (2006) (Ashton) |
| Nalox1020 | Barton, E. et al., <i>Intranasal Administration of Naloxone by Paramedics</i> , 6 Prehosp. Em. Care 54–58 (Barton 2002) |
| Nalox1021 | Barton, E. et al., <i>Efficacy of Intranasal Naloxone as a Needleless Alternative for Treatment of Opioid Overdose in the Prehospital Setting</i> , 29(3) J. Emerg. Med. 265–71 (2005) (Barton 2005) |
| Nalox1022 | Bitter, C. et al., <i>Nasal Drug Delivery in Humans</i> , 40 Curr. Probl. Dermatol. 20–35 (2011) (Bitter) |
| Nalox1023 | Boyer, E., <i>Management of Opioid Analgesic Overdose</i> , 367(2) N. Engl. J. Med. 146–55 (2012) (Boyer) |
| Nalox1024 | CDC, NDA No. 21-450 Clinical Pharmacology & Biopharmaceutics Review (2002) (Zomig Review) |
| Nalox1025 | Excerpt of Commonwealth of Kentucky, <i>Kentucky Patient Care Protocols</i> (Mar. 13, 2015) (Kentucky Patient Care Protocols) |
| Nalox1026 | Costantino, H. et al., <i>Intranasal Delivery: Physiochemical and Therapeutic Aspects</i> , 337 Int'l. J. of Pharm. 1–24 (2007) (Constantino) |
| Nalox1027 | Dowling, J. et al., <i>Population Pharmacokinetics of Intravenous, Intramuscular, and Intranasal Naloxone in Human Volunteers</i> , 30(4) Ther. Drug. Monit. 490–96 (2008) (Dowling) |
| Nalox1028 | FDA, Center for Drug Evaluation and Research, Guidance for Industry, <i>Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products – Chemistry, Manufacturing, and Controls Documentation</i> (2002) (2002 FDA Guidance) |

| Exhibit Number | Description |
|-----------------------|--|
| Nalox1029 | FDA, Center for Drug Evaluation and Research, Guidance for Industry, <i>Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action</i> (2003) (2003 FDA Guidance) |
| Nalox1030 | Freise, K. et al., <i>Naloxone Reversal of an Overdose of a Novel, Long-Acting Transdermal Fentanyl Solution in Laboratory Beagles</i> , 35(2) J. Vet. Pharmacol. Therap. 45–51 (2012) (Freise) |
| Nalox1031 | Glende, O., <i>Development of non-injectable naloxone for pre-hospital reversal of opioid overdose: A Norwegian project and a review of international status</i> (May 2016) (unpublished M.A. thesis, Norwegian University of Science and Technology) (on file with Norwegian University of Science and Technology) (Glende) |
| Nalox1032 | Hertz, S., <i>Naloxone for Outpatient Use: Data Required to Support an NDA</i> , PowerPoint Presentation (Hertz Presentation) |
| Nalox1033 | Intentionally left blank |
| Nalox1034 | Kelly, A-M. et al., <i>Randomised Trial of Intranasal Versus Intramuscular Naloxone in Prehospital Treatment for Suspected Opioid Overdose</i> , 182(1) Med. J. Austl. 24–27 (2005) (Kelly) |
| Nalox1035 | Kerr, D. et al., <i>Intranasal Naloxone for the Treatment of Suspected Heroin Overdose</i> , 103 Addiction 379–86 (2008) (Kerr 2008) |
| Nalox1036 | Kerr, D. et al., <i>Randomized Controlled Trial Comparing the Effectiveness & Safety of Intranasal & Intramuscular Naloxone for the Treatment of Suspected Heroin Overdose</i> , 104 Addiction 2067–74 (2009) (Kerr 2009) |
| Nalox1037 | Kleiman-Wexler, R. et al., <i>Pharmacokinetics of Naloxone-An Insight into the Locus of Effect on Stress-Ulceration</i> , 251(2) J. Pharmacol. Exp. Ther. 435–38 (1989) (Kleiman-Wexler) |
| Nalox1038 | Marple, B. et al., <i>Safety Review of Benzalkonium Chloride Used as a Preservative in Intranasal Solutions: An Overview of Conflicting Data and Opinions</i> , 130 Otolaryngol Head Neck Surg. 131–41 (2004) (Marple) |
| Nalox1039 | Merck Index, <i>Isotonic Solutions</i> , MISC-47–69 (Windholz, M. et al. eds., 10th ed. 1983) (Merck Index) |

IPR2019-00688 – U.S. Patent No. 9,468,747
Updated Exhibit List

| Exhibit Number | Description |
|-----------------------|--|
| Nalox1040 | Merlin, M. et al., <i>Intranasal Naloxone Delivery is an Alternative to Intravenous Naloxone for Opioid Overdoses</i> , 28 Am. J. Emerg. Med. 296–303 (2010) (Merlin) |
| Nalox1041 | Middleton, L. et al., <i>The Pharmacodynamic & Pharmacokinetic Profile of Intranasal Crushed Buprenorphine & Buprenorphine/Naloxone Tablets in Opioid Abusers</i> , 106(8) Addiction 1460–73 (2011) (Middleton) |
| Nalox1042 | Monitto, C. et al., <i>The Optimal Dose of Prophylactic Intravenous Naloxone in Ameliorating Opioid-Induced Side Effects in Children Receiving Intravenous Patient-Controlled Analgesia Morphine for Moderate to Severe Pain: A Dose Finding Study</i> , 113(4) Anesthesia & Analgesia 834–42 (2011) (Monitto) |
| Nalox1043 | <i>Pharmacodynamic Agents</i> , in Foye’s Principles of Medicinal Chemistry, 670 (Lemke, T. et al. eds., 6th ed. 2008) (Lemke) |
| Nalox1044 | Physicians’ Desk Reference, <i>NARCAN [Naloxone Hydrochloride Injection, USP]</i> , <i>IMITREX Nasal Spray [Sumatriptan]</i> , 1300–02, 1546–50 (57th ed., 2003) (PDR 2003) |
| Nalox1045 | Physicians’ Desk Reference, <i>ZOMIG Nasal Spray [Zolmitriptan]</i> , 768–78 (64th ed., 2010) (PDR 2010) |
| Nalox1046 | Robertson, T. et al., <i>Intranasal Versus Intravenous Naloxone for Prehospital Narcotic Overdose</i> , Abstract, 12(5)(1) Acad. Emerg. Med. 166–67 (2005) (Robertson 2005) |
| Nalox1047 | Robertson, T. et al., <i>Intranasal Naloxone is a Viable Alternative to Intravenous Naloxone for Prehospital Narcotic Overdose</i> , 13 Prehosp. Emerg. Care 512–15 (2009) (Robertson 2009) |
| Nalox1048 | <i>Role of Naloxone in Opioid Overdose Fatality Prevention; Public Workshop; Request for Comments</i> , 76 Fed. Reg. 71,348 (Nov. 17, 2011) (Role of Naloxone Fed. Reg. Notice) |
| Nalox1049 | <i>Role of Naloxone in Opioid Overdose Fatality Prevention</i> FDA Meeting Transcript (Apr. 12, 2012) (2012 FDA Meeting) |
| Nalox1050 | Rosanske, T., <i>Morphine</i> , in Chemical Stability of Pharmaceuticals: A Handbook for Pharmacists, 604–11 (Connors, K. et al. eds., 2d ed. 1986) (Rosanske) |
| Nalox1051 | Sabzghabae, A. et al., <i>Naloxone Therapy in Opioid Overdose Patients: Intranasal or Intravenous? A Randomized Clinical Trial</i> , 10(2) Arch. Med. Sci. 309–14 (2014) (Sabzghabae) |

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